510(k) Summary (K121173) **Date: July 8, 2012**

Company Name, Address and Contacts

AUG 16 2012

On-X Life Technologies, Inc.
1300 East Anderson Lane, Bldg B
Austin, TX 78752
Telephone: 512-339-8000 X226
Contact Person: John Ely

Establishment Registration Number: 1649833

Device Information

Proprietary Name:	Chord-X ePTFE Suture
Common Name:	ePTFE suture for chordae tendineae repair or replacement
Classification Name:	Non-absorbable expanded polytetrafluoroethylene surgical suture
Classification Panel:	Cardiovascular
Classification:	21CFR878.5035 Product code: PAW
Class:	II

Substantial Equivalence:

Gore-Tex ePTFE Suture – P820083 subsequently reclassified
Osteogenics Cytoplast ePTFE Suture – K072076

Device Description

The device is a non-absorbable monofilament ePTFE suture provided in the following configurations and meeting the USP standards:

USP 2-0 with 3/8 circle needle (Model – CX2038A)
USP 2-0 with ½ circle needle (Model – CX2012A)
USP 3-0 with 3/8 circle needle (Model – CX3038A)
USP 3-0 with ½ circle needle (Model – CX3012A)

It is provided as a sterile, single use product and contains no dyes or additives.

Intended Use

Chord-X ePTFE suture is indicated to be used in repair or replacement of chordae tendinae.

Summary of Technological Characteristics

Characteristic	Chord-X ePTFE Suture	Gore-Tex Suture for Chordae Tendineae	Osteogenics – Cytoplast Suture
Material(s)	ePTFE monofilament	ePTFE monofilament	ePTFE monofilament
Intended Use	Chordal repair	Chordal repair	Cardiovascular soft tissue
Meets USP	Yes	No - differs in diameter and knot pull strength	Yes
Configuration	USP 2-0 and 3-0	CV-4 CV-5 (approx. 2-0 and 3-0)	USP 4-0
Needle Choices	3/8 and ½ circular taper point	½ circular taper point	½ circular taper point
Packaging	Double peel-pouch type	Same type	Same type
Knot Pull Tensile Strength (2-0)	4.85 lbf	3.99 lbf	--
Stiffness	62779 kgf	35814 kgf	--
% Elongation	2.23%	3.30%	--
Usage	Single use	Single use	Single use
Sterilized	EtO	EtO	EtO
Shelf Life	3-year	3-year	Unknown

Biological Test Data of Chord-X Suture

Biological Endpoint	Results
Cytotoxicity	Grade 0, Non-Cytotoxic
Sensitization	Non-Sensitizer
	Non-Sensitizer
Intracutaneous Irritation	Nonirritant
	Nonirritant
Acute Systemic Toxicity	No signs of acute, systemic toxicity
	No signs of acute, systemic toxicity

Biological Endpoint		Results
Material Mediated Pyrogenicity		Nonpyrogenic
Hemocompatibility	ASTM Hemolysis – Direct Contact	Nonhemolytic
	ASTM Hemolysis - Extraction	Nonhemolytic
	C3a Complement Activation	Not an activator
	SC5b-9 Complement Activation	Not an activator

Physicochemical Results following Exhaustive Extraction of the Chord-X Suture

Extraction Vehicle	Sample Amount	Number of Extractions	Residue Mass	Residue Mass/cm Length
PW	123.7 cm^2 89.5 cm length	2	0.2 mg	0.002 mg
Ethanol	127.2 cm^2 90.0 cm length	2	0.4 mg	0.004 mg
Hexane	127.2 cm^2 89.5 cm length	2	0.5 mg	0.006 mg

Infrared Scans of the Residues Obtained from the Chord-X Suture

Extraction Vehicle	IR Match	NAMSA Lab Number
PW	No major bands detected	12T_20903_15
Ethanol	No major bands detected	12T_20903_16
Hexane	No major bands detected	12T_20903_17

Shelf Life

Testing to validate shelf life for Chord-X final packaging was also conducted by LSO as per the requirements listed in ISO 11607-1. An accelerated aging method per the appropriate reference standard has been employed to simulate actual shelf life duration to 3-years. Sterile barrier and product integrity tests confirm that the package is robust enough to withstand shipping and storage for at least 3-years.

Sterilization

Ethylene oxide (EO) is used to sterilize the Chord-X Suture and the process is validated to ISO 11135-1. The sterilization validation established that the process and product meet the requirements of the standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 16 2012

On-X Life Technologies, Inc.
c/o Mr. John Ely
Executive Vice President
Regulatory Affairs and Quality Assurance
1300 East Anderson Ln.
Austin, TX 78752

Re: K121173
Trade/Device Name: Chord-X ePTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: PAW
Dated: July 8, 2012
Received: August 9, 2012

Dear Mr. Ely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121173

Device Name: Chord-X ePTFE Suture

Indications For Use:

Chord-X ePTFE Suture for chordae tendinae repair or replacement is indicated for the repair or replacement of chordae tendinae.

Prescription Use __Yes_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121173